APR 13 2012

K120972
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Section 5 - 510(k) Summary

Submission Date:	**15 February 2012**
Submitter:	Phillip R. Rose Director of Quality Systems and Regulatory Affairs Tactile Systems Technology, Inc. 1331 Tyler Street NE, Suite 200 Minneapolis, MN 55413 Phone: (612) 355-5100
Contact person:	Phillip R. Rose
Name of Device:	Flexitouch® system
Classification:	Compressible Limb Sleeve (21 CFR 870.5800)
Predicate Device:	Tactile Systems Technology, Inc. Flexitouch® system Model PD32-120 (K013061) and subsequent 510(k) (K062818) for additional indication for use.

Description of Device:

The Flexitouch® system is a prescription pneumatic compression system consisting of a garment set and a pneumatic sequential controller. The garments are wrapped around the affected body regions so that the garment fits snugly. The garments have multiple chambers that are filled with air to provide for low-level compression in the treated areas.

Intended Use:

The Flexitouch® system is intended for use by medical professionals and patients at home who are under medical supervision in treating many conditions such as:

- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports issues
- Post immobilization edema
- Venous insufficiencies
- Lymphedema
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers

Comparison of Technological Characteristics:

The Flexitouch® system has the same technological characteristics to the predicate device with respect to:

- intended use
- performance
- design
- materials used
- construction
- energy source
- sterility
- labeling

and raises no new safety and/or effectiveness concerns.

Summary of Testing to Internationally Recognized Standards:

The Flexitouch® system has been tested and certified compliant to the following standards:

- IEC 60601-1: Medical Electrical Equipment - General Requirements for Safety
- EN 60601-1-2:Medical Electrical Equipment - General Requirements for Safety Electromagnetic Compatibility
- ISO 13485: Medical Devices – Quality Management Systems- Requirements for Regulatory Purposes
- 93/42/EEC: Medical Devices Directive – CE Marking

Summary of Additional Performance Testing:

Comparative performance testing and evaluation was successfully completed to verify the substantial equivalence between the Flexitouch® system, and the predicate device. This includes:

- Software validation testing,
- Device performance testing
- Device Hazard Analysis
  - Risk assessment
  - Design and process FMEA.
- Product shipping tests per ASTM D4169

Substantial Equivalence Conclusion:

Device testing and evaluation has demonstrated that the Flexitouch® system raises no new safety and/or effectiveness concerns and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 13 2012

Tactile System Technology, Inc.
c/o Mr. Ned Devine
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062

Re: K120972
Trade/Device Name: Flexitouch® System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeves
Regulatory Class: Class II
Product Code: JOW
Dated: March 29, 2012
Received: April 2, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

Indications for Use

510(k) Number (if known): K120972

Device Name: Flexitouch® system

Indications For Use:

The Flexitouch® system is intended for use by medical professionals and patients who are under medical supervision, in treating many conditions such as:

- Primary lymphedema
- Post mastectomy edema
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- Post immobilization edema
- Venous insufficiencies
- Lymphedema.
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) OR Over the Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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